K121990

AUG 3 2012

Navilyst Medical

26 Forest Street
Marlborough, MA 01752
Tel 508.658.7990

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510(k) Summary for the PICC Convenience Kit

Date prepared: 5 July 2012

A. Sponsor

Navilyst Medical, Inc.
26 Forest Street
Marlborough, MA 01752

B. Contact

Marion W. Gordon Sr. Manager Global Regulatory Affairs Phone: 508-658-7942	or	Lorraine M. Hanley Vice President Global Regulatory Affairs Phone: 508-494-1129

C. Device Name

Trade Name:	PICC Convenience Kit
Common/Usual name:	PICC Convenience Kit
Classification Name:	Catheter, Intravascular Therapeutic, short and long-term greater than 30 days 21 CFR §880.5970, Class II
Classification Panel:	General Hospital Device Panel

D. Predicate Device

Trade Name:	PICC Convenience Kit
Common/Usual name:	Peripherally Inserted Central Catheter (PICC)
Classification Name:	Catheter, Intravascular Therapeutic, short and long-term greater than 30 days 21 CFR §880.5970, Class II
Premarket Notification	K111906, K101326, K093366, K091261, K070002, K021704

E. Device Description

The PICC Convenience Kit includes packaging configurations that will accommodate a specified NMI PICC and other legally marketed procedural aides typically used during clinical placement.

F. Intended Uses

- PICC Convenience Kit with Xcela® Hybrid with PASV® Valve Technology:

for short or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, and for power injection of contrast media. Non-valved lumens are indicated for central venous pressure monitoring. The maximum power injection flow rate for the Xcela Hybrid PICC with PASV Valve Technology is 6 mL/sec.

- PICC Convenience Kit with NMI PICC II; or with NMI PICC; or with BSC PICC:

for short or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, and for power injection of contrast media.

- PICC Convenience Kit with Vaxcel® PICC with PASV® Valve Technology:

for use in establishing peripheral access to the central venous system for administration of fluids including, but nor limited to hydration agents, antibiotics, chemotherapy, analgesics, nutritional therapy, and blood products. It is also indicated for blood specimen withdrawal. The product is intended for central venous access in adults, children, and infants who require intravenous (IV) therapy.

G. Summary of Similarities and Differences in Technological Characteristics and Performance

Similarities
The proposed PICC Convenience Kit contains one of the identified predicate PICCs packaged with a variety of procedural aide componentry typically used during PICC placement.

Differences
The proposed packaging configurations differ from the predicate PICC packaging in order to contain a broader selection of procedural aides used in PICC placement. All packaging is manufactured from packaging materials that are well characterized and commonly used in the medical industry.

H. Performance

No performance standards have been established under section 514 of the Food, Drug and Cosmetic Act for these devices. The performance evaluation of the PICC Convenience Kit was conducted based upon a risk analysis and included testing conducted in accordance with the following national/international standards and FDA guidance documents:

- AAMI/ANSI/ISO *Biological evaluation of medical devices—Part 7: Ethylene oxide sterilization residuals* (2008)
- AAMI/ANSI/ISO 11601-1 *Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems, and packaging systems* (2006)
- AAMI/ANSI/ISO 11601-2 *Packaging for terminally sterilized medical devices Part 2: Validation requirements for forming, sealing and assembly processes* (2006)
- FDA's *Convenience Kits, Interim Regulatory Guidance: 20 May 1997*
- FDA's *Sterilized Convenience Kits for Clinical and Surgical Use: 7 January 2002*

I. Safety and Performance Testing

The successful results of the following key tests demonstrate that the proposed NMI PICC Convenience Kits have met the pre-determined acceptance criteria applicable to the safe use of the devices.

Tests:

1. Packaging Standards Testing
2. EO Sterilization Testing

J. Conclusion

Results of testing according to recognized standards and in consideration to the responses posed in FDA's *Guidance on the CDRH Premarket Notification Review Program, 510(k) Decision Making Tree*, the proposed PICC Convenience Kit is determined to be substantially equivalent to the predicate NMI PICCs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Marion W. Gordon
Senior Manager, Global Regulatory Affairs
Navilyst Medical Incorporated
26 Forest Street
Marlborough, Massachusetts 01752

AUG 3 2012

Re: K121990
Trade/Device Name: PICC Convenience Kit
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: July 5, 2012
Received: July 6, 2012

Dear Ms. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

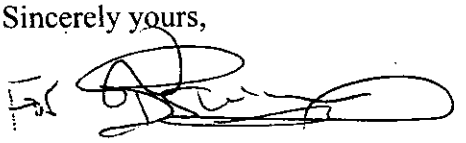
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if Known): _____

Device Name: PICC Convenience Kit

with Xcela® Hybrid PICC with PASV® Valve Technology

Indications for Use:

for short- or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, and for power injection of contrast media. Non-valved lumens are indicated for central venous pressure monitoring. The maximum power injection flow rate for the Xcela Hybrid PICC with PASV Valve Technology is 6 mL/sec.

Prescription Use (21 CFR 801 Subpart D) ☒ And/Or AND/OR Over-The-Counter Use: (21 CFR 801 Subpart C) ☐

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

8/2/12

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K121990

Indications for Use

510(k) Number (if Known): _____

Device Name: PICC Convenience Kit
with NMI PICC II
Or
with NMI PICC
Or
with BSC PICC

Indications for Use:

for short or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, and for power injection of contrast media.

Prescription Use (21 CFR 801 Subpart D) ☒ And/Or AND/OR Over-The-Counter Use: (21 CFR 801 Subpart C) ☐

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Concurrence of CDRH, Office of Device Evaluation (ODE)

RLH C Chyna 8/2/12

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K121990

Indications for Use

510(k) Number (if Known): _____

Device Name: PICC Convenience Kit

with Vaxcel® PICC with PASV® Valve Technology

Indications for Use:

for use in establishing peripheral access to the central venous system for administration of fluids including, but nor limited to hydration agents, antibiotics, chemotherapy, analgesics, nutritional therapy, and blood products. It is also indicated for blood specimen withdrawal. The product is intended for central venous access in adults, children, and infants who require intravenous (IV) therapy.

Prescription Use (21 CFR 801 Subpart D) ☒ And/Or AND/OR Over-The-Counter Use: (21 CFR 801 Subpart C) ☐

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Concurrence of CDRH, Office of Device Evaluation (ODE)

8/2/12

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K121998